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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,972

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EXAMINER

METZMAIER, DANIEL S

ART UNIT

PAPER NUMBER

1762

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06/23/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,972	Applicant(s) WORLE ET AL.	
	Examiner DANIEL S. METZMAIER	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2011 & 13 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11 and 13-32 is/are pending in the application.
- 4a) Of the above claim(s) 15-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/7/2011 & 4/13/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7, 9-11 and 13-32 are pending.

Election/Restrictions

1. Claims 15-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups II, IV, and V, there being no allowable generic or linking claim. Election has been treated **without** traverse in the reply filed on 09 September 2010 since the only traversal relates to Group III, claim 14, which has been collapsed into Group I, claims 1-13. Claims 1-14 have been examined on the merits.

2. This application contains claims 15-32 drawn to an invention nonelected with traverse in the reply filed on 09 September 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not properly identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

The Declaration only provides the filing date for priority document GB 0318244.1. The remaining priority documents are not properly identified.

Claim Interpretations

4. Claims 1-14 are directed to methods of forming dispersions and drying said dispersion. Claim 1 is representative as follows:

1. (Original) A method for forming a dispersion comprising non-lamellar amphiphile particles having improved phase behaviour, particle size distribution and/or storage stability, said method comprising
forming a dispersion of lamellar and optionally non-lamellar particles comprising at least one structuring agent in a polar solvent,
heating said particles to a temperature of 80 to 150° for a time of one minute to four hours, followed by
cooling,
after cooling thereby providing a measurable improvement in phase behaviour, particle size distribution and/or storage stability.

The limitations to “improved phase behaviour, particle size distribution and/or storage stability” and “measurable improvement in phase behaviour, particle size distribution and/or storage stability” have been considered and given little patentable weight since they are un-quantified.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

6. Claim 14 is rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it

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depends, or for failing to include all the limitations of the claim upon which it depends.

Claim 1 is directed to methods of forming dispersions, while claim 14 is directed to a process step comprising drying said particles. Applicants assert that drying does not need to result in dry particles. This has not been deemed persuasive since the act of drying the particles necessarily destroys the dispersion to achieve the result of drying of the particles. Applicants' characterization resembles concentrating, which has not been claimed. Claim 14 is outside of the metes and bounds of claim 1 and fails to further limit claim 1, which claim 14 depends.

Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 3-5, 9-11 and 13-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morancais et al, US 5,670,099. Morancais et al (column 10, lines 20-34) discloses the process of claim 1, wherein:

In accordance with a particular embodiment of the present invention, a lamellar phase is prepared, by dissolving the lipid(s) in a solvent before forming the wall of the vesicles, evaporating the solvent under reduced pressure, then admixing the lipidic combination thus formed with the aqueous phase E, homogenizing and heating the mixture to a temperature of 10 °-150 ° C, preferably 40 ° -80 ° C, for 0.25 hours and returning the temperature to ambient temperature. **The cycle: homogenization-heating-return to ambient temperature is repeated at least once.** There is advantageously employed, as solvent, dichloromethane, chloroform, ethyl acetate, butyl acetate, ethyl formate, hexane, cyclohexane, toluene, petroleum ether, methanol, ethanol, propanol, methyl ether, ethyl ether and mixtures of at least two of them.

The equilibrium phases at higher temperatures and improved phase behavior, particle size distribution and/or storage stability would have been inherent since all the other elements of the process are clearly disclosed in the Morancais et al reference.

To the extent the Morancais et al reference differs from the claims in a lack of the non-lamellar phase, Morancais et al discloses the same process and would have been expected to form non-lamellar phases at the phase transition temperature, which would have been expected to vary based on the amphiphiles, polar solvent, further additives and concentrations thereof, which are known to affect the lamellar stability.

11. Claims 1-7, 9-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (I), US 6482517, in view of Anderson (II), US PG PUB 2003/0232340, in view of Morancais et al, US 5,670,099.

Anderson (I) (example 10) discloses processes substantially as claimed.

Anderson (II) (paragraph [0057]) teaches:

“ . . . the present inventor described methods for producing dispersions of coated particles of a wide range of liquid crystalline phases including cubic and hexagonal. These methods include chemical reactions, heating-cooling temperature cycles . . . ”,

when referencing 09/297,997 now Anderson (I), US 6482517.

Anderson (I) differs from the claims in the specific disclosure of the crystalline phases of the dispersions. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to perform the Anderson (I) process for the advantages taught in Anderson (II) and the products contemplated therein. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality for a result-effective variable, *i.e.*, a variable which achieves a recognized result.

Morancais et al (column 10, lines 20-34) discloses performing the homogenizing and heating the mixture to a temperature of 10 °-150 ° C, preferably 40 ° -80 ° C, for 0.25

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hours and returning the temperature to ambient temperature and performing “The cycle: homogenization-heating-return to ambient temperature is **repeated at least once**”.

Response to Arguments

12. Applicant's arguments filed 13 April 2011 have been fully considered but they are not persuasive.

13. Applicants (pages 8 and 9) assert that the term lamellar and non-lamellar phases have been overlooked and the Morancais et al reference is directed to making lamellar or vesicles and it is further asserted by applicants that the examiner has overlooked the claimed requirement of the structuring agent.

Initially, applicants structuring agent is characterized in the specification as forming lamellar phases and are amphiphilic compounds.

Applicants characterization of the lamellar and non-lamellar phases are not quantified and the lamellar compositions would not be expected to be ideal or completely thermodynamically stable.

Applicants have not presented any evidence or persuasive reasoning how said broad and relative language to improved distribution, behavior or storage stability patentably distinguishes over the prior art methods that perform the same steps on the same materials.

The times and temperatures are clearly taught in those claim elements clearly read on those parameters disclosed in the Morancais et al reference.

Applicants make similar arguments regarding the Anderson (I) and (II) references. These have not been deemed persuasive for the same reasons herein above.

14. Applicant's remaining arguments with respect to claim 1-7, 9-11 and 13-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (571) 272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David W. Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Daniel S. Metzmaier/
Primary Examiner, Art Unit 1762**

DSM